Catheter Connections, Inc.
Donald D. Solomon
President and COO
615 Arapeen Drive, Suite 302a
Salt Lake City, Utah 84108

March 11, 2022

Re: K113842
Trade/Device Name: Catheter Connections' Dualcap Solo
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Donald D. Solomon:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 27, 2012 and the correction letter dated December 14, 2018. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation 880.5440.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

Payal Patel
Assistant Director for General Hospital Devices
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

FDA U.S. FOOD & DRUG ADMINISTRATION

December 14, 2018

Catheter Connections, Inc.
Donald Solomon
President and CEO
2455 E Parleys Way - Suite 150
Salt Lake City, Utah 84109

Re: K113842
Trade/Device Name: Catheter Connections' Dualcap Solo
Regulatory Class: Unclassified
Product Code: QBP
Dated: December 22, 2011
Received: December 28, 2011

Dear Donald Solomon:

This letter corrects our substantially equivalent letter of January 27, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications For Use

510(k) Number (if known): _____

Device Name: **Catheter Connections' DualCap Solo™**

Indications For Use:

When left in place for five (5) minutes, DualCap Solo™ disinfects needleless luer access valves; thereafter the caps provide a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

1/25/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113842

JAN 2 7 2012 K113842

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(21 CFR 807.92)

for Catheter Connections' DualCap Solo™

SUBMITTER:

Catheter Connections, Inc.
615 Arapeen Drive, Suite 302a
Salt Lake City, UT 84108

ESTABLISHMENT REGISTRATION NUMBER:
3009141010

CONTACT:

Donald D. Solomon, Ph.D.
President and COO
Telephone: (801) 209-1269
Fax: (888) 862-2693
Email: dsolomon@cathconn.com

DATE PREPARED:
September 30, 2011

MODIFIED DEVICE (Submission Device):

Trade Name:	DualCap Solo™
Regulation Number:	Unclassified
Regulation Classification Name:	Pad, Alcohol, Device Disinfectant
Regulatory Class:	Unclassified
Classification Product Code:	LKB
Classification Advisory Panel:	General Hospital

SPONSOR'S CLEARED DEVICE – DualCap™ (K093229):

510(k) Holder of CLEARED DEVICE (K093229): Catheter Connections, Inc.

Regulation Number:	Unclassified
Regulation Classification Name:	Pad, Alcohol, Device Disinfectant
Regulatory Class:	Unclassified
Classification Product Code:	LKB
Classification Advisory Panel:	General Hospital

DEVICE DESCRIPTION:

The DualCap Solo™ is designed to fit securely on luer access valves. The cap contains 70% isopropyl alcohol. The product is intended for single-use and is provided sterile, this device is not made with natural rubber latex, non-pyrogenic, preservative free and DEHP free.

INTENDED USE:

DualCap Solo™ is intended for use on luer access valves. DualCap Solo™ will disinfect and decontaminate the valve and act as a barrier to contamination between IV administration line accesses.

DualCap Solo™ will disinfect the connections within five (5) minutes after application and act as a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

INDICATIONS FOR USE:

When left in place for five (5) minutes DualCap Solo™ disinfects needleless luer access valves; thereafter the caps provide a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

New device is compared to Marketed Device? Yes. It is compared to legally marketed predicates (Sponsor's Cleared Device).

Does the new device have the same indication statements? Yes.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)? No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Yes. The Catheter Connections' DualCap Solo™ is substantially in equivalent design, materials, packaging, sterilization method and method of operation. The basic fundamental scientific technology of the device has not changed.

Could the new characteristics affect safety or effectiveness? No.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

Sterilization requirements of ISO 11137: 2006, Sterilization of health care products – Radiation.

Biocompatibility requirements according to of ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics? Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards and protocols.

Do performance data demonstrate equivalence? Yes. Performance data gathered demonstrated that the Catheter Connections' DualCap Solo™ is substantially equivalent to the noted predicate (Sponsor's Cleared Device – DualCap™).

CONCLUSION

The Catheter Connections' DualCap Solo™ will meet all established acceptance criteria for performance testing. This testing demonstrated that the Catheter Connections' DualCap Solo™ is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the above noted Sponsor's Cleared Device (DualCap™ - K093229).